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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,935	11/01/2001	Robert Eric Montgomery	P1088US011	9955
53096 7590 11/20/2007 DISCUS DENTAL IMPRESSIONS, INC. 8550 HIGUERA STREET CULVER CITY, CA 90232			EXAMINER JAGOE, DONNA A	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 11/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/039,935	Applicant(s) MONTGOMERY, ROBERT ERIC	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-58, 61-65, 67-76 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-58, 61-65, 67-76 and 78-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' arguments filed September 4, 2007 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 56-58, 61-65, 67-76 and 78-81 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56-58, 61-65 and 67-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, "including a chelating agent" (present claims 56 and 71) is a concept that was not present in the specification as originally filed. Therefore it is considered new matter. Applicants are advised that the issue here is not whether particular instances of **calcium** chelating agent are found, but rather whether the concept of **any** chelating

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agent was present in the specification as originally filed. The Examiner contends that support for any chelating agent was not present in the specification as originally filed. The specification as originally filed contains the following disclosures concerning chelating agents:

- (i) "...The matrix comprises a thickening agent, an agent for stabilizing the hydrogen peroxide-containing compound, a pH adjusting agent 25 and a calcium chelating agent." (page 4, lines 23-25);
- (ii) "...a calcium chelating agent is included in the composition to prevent precipitation of calcium ions. (Table 1-4) " (page 6, lines 1-4);
- (iii) "...examples of calcium chelating agents include any of the calcium chelating agents known in the art" (page 6, lines 8-9);
- (iv) "...calcium chelating agents may prevent this precipitation of calcium ions with the associated observed improvement of tooth bleaching effect." (page 6, lines 17-18);
- (v) "...more particularly 8-9.5 that includes a calcium chelating agent " (page 7, line 11).
- (vi) "... positive effect of the calcium chelating agent on tooth bleaching..." (page 14, line 1)

The above disclosures, however, do not provide adequate support for any chelating agent. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention.

Lockwood v. American Airlines, Inc., 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

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The Examiner is guided in his opinion that Applicant has not adequately described the presently claimed subject matter by the MPEP at § 2163 - 2163.05. In particular, while Applicant's specification as originally filed contained a teaching of calcium chelating agents. Applicants now claim a chelating agent. Because such represents a genus that were not previously set forth or that would have been immediately envisaged by one skilled in the art from the specification as originally filed. "A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996)"(emphasis added), see MPEP § 2163(I)(A). Also, "See also *In re Smith*. 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ('Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads.' (emphasis added)).", see MPEP § 2163.05(II).

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set for the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of a "chelating agent". A chelating agent that has two coordinating atoms is called bidentate; one that has three, tridentate; and so

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on. EDTA, or ethylenediaminetetraacetate, one of the claimed "chelating agents" is a common hexadentate chelating agent. There is no teaching in the instant specification as to how one would choose a chelating agent, other than the calcium chelating agents set forth as in (i)-(vi) above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 81 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the "mixing baffle" of claim 81, the claim states "The dosage delivery unit of claim 78 wherein the static mixer includes a mixing baffle". It is unclear to the Examiner how the "mixing baffle" differs from the static mixer. Turning to the instant specification on page 7, lines 22-24, it states that the mixing of the two components can be readily achieved using a multi-component tube containing a baffle, otherwise known in the art as a static mixer". The way the claim is stated, one is led to believe that the baffle is a separate component comprised in the static mixer, however the instant specification describes it as one and the same. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 56-58, 61-65, 67-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christina-Beck et al. U.S. Patent No. 5,766,574 in view of Spehar et al. U.S. Patent No. 4,753,536.

Christina-Beck et al. teach a dual component whitening dentifrice composition (see abstract). The peroxide is *inter alia* sodium percarbonate (a hydrogen peroxide-containing compound) (column 3, lines 11-12) and further comprises thickeners, such as block copolymers having a molecular weight of 4000 (column 3, lines 47-67), water in an amount of from 5 to 30% (column 3, lines 42-46), and chelating agents such as sodium acid pyrophosphate (column 4, lines 1-10). It does not teach a stabilizing agent, however, it is noted that the stabilizing agent instantly claimed in claim 63 is sodium acid pyrophosphate, which is present in the composition of Christina-Beck as a chelating agent. "Products of identical chemical composition (i.e. sodium acid pyrophosphate) can not have mutually exclusive properties." A chemical composition

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and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. a stabilizing agent) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

The pH of the formulation is in the range of 5 to 8, which overlaps and partially encompasses claims 58 (pH greater than 5.5), claim 67 (pH within a range of between 6 and 10), claim 68 (pH within a range of between 7 and 10) and claim 69 (pH within a range of between 8 and 9.5).

Christina-Beck et al. differs in that it does not teach an alkaline pH-adjusting agent per se. However, the pH of the dentifrice partially overlaps and encompasses the pH range of the instant claimed dosage delivery unit as noted above. The criticality of the specific alkaline pH-adjusting agents has not been disclosed. In the absence of any criticality and/or unexpected results of the instantly claimed alkaline pH-adjusting agents of claim 62, the instant invention is considered obvious.

Christina-Beck et al. does not teach the amount of water to be at least 70% water by weight, based on the weight of the mixture (claim 61). It teaches water in the peroxide component in an amount between 5 – 30% (column 3, lines 42-46) and in the abrasive component in an amount between 10 and 20% (column 4, lines 40-41) to total

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about 15 to 50% water. As anyone of ordinary skill in the art will appreciate, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find *workable* conditions generally involves no more than the application of routine skill in the art of chemical engineering. See, only as exemplary, the dicta of *In re Aller* 105 USPQ 233. Similarly, the determination of *optimal* values within a disclosed range is generally considered obvious. See, only as exemplary, the dicta of *In re Boesch* 205 USPQ 215. For these and other self-evident reasons, it would have been obvious to add water greater than 70%.

Regarding the static mixer of the device, Christina-Beck et al. differs in that there is not a mixing baffle/static mixer disclosed, however, Spehar et al. teach a dispensing mixer for the storage and mixing of separate materials comprising a syringe with separate compartments that discharge from a common nozzle. The Nozzle assembly comprises a static mixing element that is caused to rotate by the ingress of material fed through the nozzle (see abstract). Since the static mixer was well known it would have been obvious to employ a static mixer to mix the dual component composition of Christina-Beck et al since it teaches that the components are "maintained separate from the other until dispensed and combined for application to teeth requiring whitening" (see abstract).

In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. This motivation may flow from the prior art

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references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Here, filtered through the prior art references and the nature of the problem to be solved, Christina-Beck disclosed that components are "maintained separate from the other until dispensed and combined for application to teeth requiring whitening" (see abstract), Spehar et al. teach a dispensing mixer for the storage and mixing of separate materials comprising a syringe with separate compartments that discharge from a common nozzle and comprises a mixing baffle for mixing the separate materials. The particular known technique of a mixing baffle attached to a dispensing container was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to the dentifrice of Christina-Beck et al. that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. The gap between the prior art and Applicants' system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.

Response to Arguments

Applicant states that it is true that a calcium chelating agent is fully disclosed as noted by the Examiner, but states that there is sufficient support in the disclosure as filed for a chelating agent in general. In response, the Examiner points in particular to paragraph [0039] wherein it is stated "The table further shows the positive effect of the **calcium** chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating

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agent. There was an observed improvement in AE in the presence of **the** chelating agent. The best tooth bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.” It is abundantly clear to the examiner that the instant application is stating the benefits of a “**calcium** chelating agent”. Not just any chelating agent.

Applicant's arguments regarding the 112 2nd paragraph rejection of claim 81 have been fully considered but they are not persuasive. There is no other description or recitation of a separate mixing baffle other than as stated in the specification on page 7 “The mixing of the two components can be readily achieved using a multi-component-tube containing a baffle, **otherwise known in the art as a static mixer** such that on squeezing the tube, material from each of the compartments is forced through the static mixer and are mixed together before emerging from a single exit in the tube”. Applicant states that there are many different versions, including a mixing baffle. While applicant may be correct in this statement, there is not support for many different versions in the instant application. There is only one baffle disclosed, “otherwise known in the art as a static mixer” (see specification page 7).

In response to applicant's argument that Christina-Beck et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, like the instant invention, the components are held in a multi-

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chambered vessel separate, until dispensed. The problem to be solved is mixing the agents after it is dispensed because the components degrade when stored together. Christina-Beck et al. teach that the mixing of the agents is accomplished on the brush when it is dispensed. In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. This motivation may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Here, filtered through the prior art references and the nature of the problem to be solved, Christina-Beck disclosed that components are "maintained separate from the other until dispensed and combined for application to teeth requiring whitening" (see abstract), Spehar et al. teach a dispensing mixer for the storage and mixing of separate materials comprising a syringe with separate compartments that discharge from a common nozzle and comprises a mixing baffle for mixing the separate materials. The particular known technique of a mixing baffle attached to a dispensing container was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to the dentifrice of Christina-Beck et al. that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. The gap between the prior art and Applicants' system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.

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In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Donna Jagoe', with a stylized, cursive script.

Donna Jagoe

Patent Examiner

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November 15, 2007